510(K) SUMMARY K013108 1/2

1. HAKKO SHOJI CO., LTD
7-9 Kamimeguro 1-Chome, Meguro-ku
Tokyo 153 Japan
81-(3)-464-8500 Fax 81-(3)-464-8539

APR 0 4 2002

Contact person: M. Moruyama

2. DEVICE NAME
Proprietary Name(s): BioSuc
Common Name(s): Fine Aspiration Cytology Needle

Device Class: Class II
21CFR 876.1075
Aspiration biopsy needle (gastroenterology-urology biopsy instrument).
Product Code: KNW

3. STATEMENT OF SUBSTANTIAL EQUIVALENCE:
Predicate Devices:

Manan Medical Products, Inc.	Westcott Aspiration Needle K943651
Travenol Lab.	Allegiance Aspiration Needle K831392
Daum GMBH	Daum Aspiration Biopsy Needle K974575

The Biosuc Fine Aspiration Cytology Needle is substantially equivalent to the referenced predicated devices in that it is similar with respect to technological characteristics and intended use.

4. DESCRIPTION OF THE DEVICE(S)
Needle size: 20G: 50mm to 100mm, 21G: 50mm, 22G: 50mm
Needle tip: Bayonet point (Lancet point)
Suction syringe: 7 ml
Plunger slide: 35 mm
Side Hole

20G: ϕ 0.35 to ϕ 0.5 n=0 to 3
21G: ϕ 0.35 to ϕ 0.5 n=0 to 3
22G: ϕ 0.35 n=0 to 2

Product Code No.	Needle size	Side Hole	Syringe
22030500	20Gx50mm	ϕ 0.5 1 hole	7 ml
22030510	20Gx100mm	ϕ 0.5 1 hole	7 ml
22030520	21Gx50mm	ϕ 0.5 1 hole	7 ml
22030540	22Gx50mm	ϕ 0.35 1 hole	7 ml

5. STATEMENT OF INTENDED USE:
Biopsy of tumors in the Thyroid, Breast or Lymph Node, etc., and adjacent to the body surface.

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E. DESCRIPTION OF DEVICE(s):
Needle size: 20G: 50mm to 100mm, 21G: 50mm, 22G: 50mm
Needle tip: Bayonet point (Lancet point)
Suction syringe: 7 ml
Plunger slide: 35 mm
Side Hole

20G: ϕ 0.35 to ϕ 0.5 n=0 to 3

21G: ϕ 0.35 to ϕ 0.5 n=0 to 3

22G: ϕ 0.35 n=0 to 2

Product Code No.	Needle size	Side Hole	Syringe
22030500	20Gx50mm	ϕ 0.5 1 hole	7 ml
22030510	20Gx100mm	ϕ 0.5 1 hole	7 ml
22030520	21Gx50mm	ϕ 0.5 1 hole	7 ml
22030540	22Gx50mm	ϕ 0.35 1 hole	7 ml

F. PROPOSED LABELING:
See attached (Page 46)
Each Product Label will have the following information:

Complete product description

Manufactured by: Hakko Medical Co., Ltd.

Distributed by: Havel's Incorporated
3726 Lonsdale Street
Cincinnati, Oh 45227
(513) 271-2117
Made in Japan

STERILE SINGLE USE ONLY

CAUTION: Do not use if package has been opened or damaged. Store in a cool, dry place. Federal law restricts this device to sale by or on the order of a physician.

Sterile unless opened or damaged

G. STATEMENT OF INTENDED USE:
Biopsy of tumors in the Thyroid, Breast or Lymph Node, etc., and adjacent to the body surface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hakko Medical Company, Ltd.
c/o Mr. Shiro Kitagawa
Director, Marketing Division
Hakko Shoji Co., Ltd.
7-9 Kamimeguro 1-Chome
Meguro-Ku, Tokyo,
Japan 153

APR 0 4 2002

Re: K013108
Trade/Device Name: BioSuc Fine Aspiration Cytology Needle
Regulation Number: 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: December 14, 2001
Received: March 21, 2002

Dear Mr. Kitagawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013108

Device Name: BioSuc Fine Aspiration Cytology Needle

Indications For Use:

The BioSuc Fine Aspiration Cytology Needle is indicated for the biopsy of tumors in the Thyroid, Breast or Lymph node.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013108